REMARKS

This Response is being filed in connection with the Office Action mailed July 13, 2006. Claims 8 to 11, 20 and 21 are under consideration.

Regarding the Claim Amendments

Support for the amendments to claims 8 to 11, 20 and 21 can be found throughout the specification. In particular, the amendment to recite "human anti-human" is supported, for example, by originally filed claims 1 to 20, and at page 12, lines 10-11. The amendment to recite "(Alexis)" is supported, for example, at page 52, lines 1-3. Thus, as the claim amendments are supported by the specification, no new matter has been added and entry thereof is respectfully requested.

I. REJECTIONS UNDER 35 U.S.C. §112

The rejection of claims 8 to 11, 20 and 21 under 35 U.S.C. §112, second paragraph, as allegedly indefinite is respectfully traversed. Allegedly, the recitation of "CD40L enhancer antibody" is relative and therefore, indefinite.

Claims 8 to 11, 20 and 21 are clear and definite as written. In this regard, one skilled in the art would be apprised of the meaning of "enhancer" used in reference to a CD40L antibody, since enhance means to make greater or to augment. In this regard, the specification discloses the source of CD40L enhancer antibody, namely Alexis, and claims 8 to 11, 20 and 21 have been amended to recite "(Alexis)." Consequently, the meaning of CD40L enhancer antibody would be clear to the skilled artisan. Accordingly, Applicants respectfully request that rejection under 35 U.S.C. §112, second paragraph, be withdrawn.

The rejection of claims 8 to 11, 20 and 21 under 35 U.S.C. §112, first paragraph, as allegedly lacking an adequate written description is respectfully traversed. Allegedly, "the disclosure does not reasonably convey that the inventor(s) had possession of the claimed invention at the time the application was filed."

Claims 8 to 11, 20 and 21 are adequately described. In this regard, the specification discloses "human anti-CD40 antibodies and fragments," as well as anti-human CD40 antibodies or fragments (see, for example, page 4, lines 12-15 and lines 22-25). In view of the foregoing, it is clear that the originally filed specification provides and adequate written description for "anti-CD40 antibodies and fragments."

Nevertheless, solely in order to further prosecution of the application and without acquiescing to the propriety of the rejection, claims 8 to 11, 20 and 21 have been amended to recite "human anti-human" CD40 antibody. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

II. REJECTIONS UNDER 35 U.S.C. §102

U.S. Patent No. 5,874,082 (De Boer)

The rejection of claims 8 to 11, 20 and 21, under 35 U.S.C. §102(e) as allegedly anticipated by De Boer (U.S. Patent No. 5,874,082), is respectfully traversed. Allegedly, de Boer describe the claimed anti-CD40 antibodies.

deBoer fail to teach or suggest the anti-CD40 antibodies of claims 8 to 11, 20 and 21, prior to entry of the claim amendments. In this regard, claims 8 to 11, 20 and 21 require that the anti-CD40 antibodies have a minimal ability to inhibit CD40L mediated tonsillar B cell proliferation in vitro under defined assay conditions that the 5D12 antibody in deBoer does not have under identical assay conditions. In particular, claim 8 requires that the anti-CD40 antibodies have an inhibitory efficiency that leads to about 50 to 95% or greater reduction in B cell proliferation when the antibody is in a range of 0.01 ug/ml to 10 ug/ml. Claims 9 to 11 require about a 85 to 95% or greater reduction, about 80 to 95% or greater reduction, and about a 95% or greater reduction in B cell proliferation, respectively, when the antibody is in an amount up to 10 ug/ml. As previously pointed out, in direct comparison studies disclosed in the specification, 5D12 antibody does not have an inhibitory efficiency that leads to about 50 to 95% or greater reduction in B cell proliferation when in a range of 0.01 ug/ml to 10 ug/ml (Example 6 and Figure 10). In fact, 100 ug/ml of 5D12 antibody was required to achieve 50% reduction in B cell proliferation, an amount that is 10-fold greater than the maximum amount recited in claims 8 to 11, 20 and 21 (Example 6, page 55, lines 20-29). Antibody 5D12 at amounts less than 10

ug/ml did not achieve at least a 50% reduction in B cell proliferation as required of claims 8 to 11, 20 and 21 (Figure 10). Thus, because the 5D12 antibody reported in deBoer clearly fails to have the required inhibitory efficiency at the recited amounts of claims 8 to 11, 20 and 21, 5D12 antibody is clearly not within the scope of these claims.

Accordingly, because none of the antibodies mentioned in deBoer have the ability to inhibit CD40L mediated tonsillar B cell proliferation in vitro to the extent required at the recited amounts of claims 8 to 11, 20 and 21, none of the antibodies described in deBoer are within the scope of claims 8 to 11, 20 and 21. Consequently, De Boer (U.S. Patent No. 5,874,082) cannot anticipate claims 8 to 11, 20 and 21 and Applicants respectfully request that the rejection under 35 U.S.C. §102(e) be withdrawn..

Nevertheless, solely in order to further prosecution of the application and without acquiescing to the propriety of the rejection, claims 8 to 11, 20 and 21 have been amended to recite "human anti-human CD40 antibody." deBoer fail to describe a human anti-human CD40 antibody. In this regard, antibody 5D12 is a mouse antibody.

In sum, deBoer fails to teach or suggest anti-CD40 antibodies and fragments thereof required in claims 8 to 11, 20 and 21. Accordingly, claims 8 to 11, 20 and 21 are not anticipated by deBoer (U.S. Patent No. 5,874,082) and Applicants respectfully request that the rejection under 35 U.S.C. §102(e) be withdrawn.

U.S. Patent Application Publication 2004/0235074 A1 (Siegall et al.)

The rejection of claims 8 to 11, 20 and 21, under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent Application Publication 2004/0235074 A1 (Siegall *et al.*) is respectfully traversed. Allegedly, Siegall *et al.* describe the claimed anti-CD40 antibodies.

For the reasons discussed above and set forth in the record, Siegall *et al.* fail to teach or suggest the antibodies of claims 8 to 11, 20 and 21. Siegall *et al.* describe the same antagonist anti-CD40 antibodies as deBoer, namely 5D12, 3A8 and 3C6. As discussed above, in direct comparison studies, 5D12 antibody did not have the minimal inhibitory efficiency at the recited amounts as required of claims 8 to 11, 20 and 21. Since the data in deBoer indicate that antibodies 3A8, 3C6 have the same tonsillar B cell proliferation inhibitory efficiency as 5D12, and in direct comparison studies disclosed in the specification, 5D12 did not have the minimal

inhibitory efficiency at the recited amounts required claims 8 to 11, 20 and 21, none of antibodies 5D12, 3A8 or 3C6 in Siegall *et al.* have the minimal inhibitory efficiency at the recited amounts of claims 8 to 11, 20 and 21.

Accordingly, because none of the antibodies mentioned in Siegall *et al.* have the minimal inhibitory efficiency at the recited amounts required of claims 8 to 11, 20 and 21, none of the antibodies described in Siegall *et al.* are within the scope of claims 8 to 11, 20 and 21. Consequently, Siegall *et al.* (2004/0235074 A1) cannot anticipate claims 8 to 11, 20 and 21, and Applicants respectfully request that the rejection under 35 U.S.C. §102(e) be withdrawn.

Moreover, claims 8 to 11, 20 and 21 have been amended to recite "human anti-human CD40 antibody." Siegall *et al.* fail to describe a human anti-human CD40 antibody. In this regard, antibodies 5D12, 3A8 and 3C6 are mouse antibodies.

In sum, Siegall *et al.* fail to teach or suggest anti-CD40 antibodies and fragments thereof of claims 8 to 11, 20 and 21. Accordingly, claims 8 to 11, 20 and 21 are not anticipated by Siegall *et al.* (2004/0235074 A1) and Applicants respectfully request that the rejection under 35 U.S.C. §102(e) be withdrawn.

III. OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTIONS

Claims 8 to 11, 20 and 21 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 1 to 30 of U.S. Patent No. 7,063,845. Claims 8 to 11, 20 and 21 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 31 to 40, 48, 49, 51 and 52 of application serial no. 10/693,629. Claims 8 to 11, 20 and 21 also stand rejected as not patentably distinct from claims 31 to 40, 48, 49, 51 and 52 of application serial no. 10/693,629.

Applicants respectfully request that these rejections be held in abeyance until such time as allowable subject matter for this application has been indicated. Applicants will file an appropriate response, such as a Terminal Disclaimer and/or a statement regarding common ownership, upon indication of allowable subject matter.

CONCLUSION

In summary, for the reasons set forth herein, Applicants maintain that claims 8 to 11, 20 and 21 clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 509-4065.

Please charge any fees associated with the submission of this paper to Deposit Account Number 033975. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,

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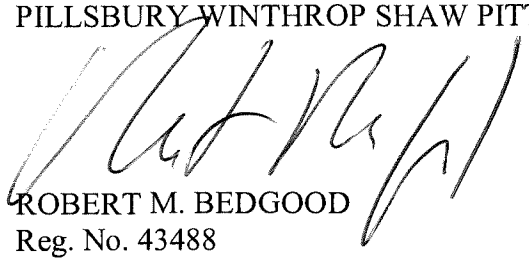

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